UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

CASE NO. 4:24-CR-00010 RLW/SPM

UNITED STATES OF AMERICA

vs.

MOHD AZFAR MALIK, M.D.
_____/

MOTION TO DISMISS

Mohd Azfar Malik, M.D., through undersigned counsel, and pursuant to Federal Rule of Criminal Procedure 12(b)(3)(B)(v), moves to dismiss every Count in the Indictment for failure to state a claim. The Government has *criminally* charged Dr. Malik for allegedly violating regulations associated with the practice of medicine. This motion demonstrates that, as a matter of law, none of the regulations were violated, necessitating dismissal.

Introduction

At all times relevant to the Indictment (and for the past 40 years), Dr. Malik was a psychiatrist licensed to practice medicine in the state of Missouri, was registered with the DEA to dispense controlled substances (including ketamine and esketamine) from his office in the Cedar Plaza Building in South St. Louis County and other locations where he practiced medicine, and was enrolled in the Medicare program. Indictment ¶¶ 1, 9, 10, 28. Dr. Asim Muhammad Ali, who occasionally performed certain services for Dr. Malik, was also a medical doctor licensed to practice medicine in the state of Missouri but was not himself registered with the

DEA. Indictment ¶¶ 2, 12. Although the Indictment opines that he should not have been, Dr. Ali also was enrolled in the Medicare program. Indictment ¶¶ 29, 32.

What makes Dr. Malik and Dr. Ali drug traffickers, according to the Indictment, is that, on a handful of occasions, Dr. Ali administered ketamine and esketamine to Dr. Malik's patients from what the Indictment claims was the wrong suite in the Cedar Plaza Building when Dr. Malik was not physically present. And what makes Dr. Malik and Dr. Ali fraudsters, according to the Indictment, is that Dr. Malik submitted a handful of claims to Medicare for services Dr. Ali performed for Dr. Malik's patients. According to the Indictment, these actions violated federal and state regulations. As explained in our related Motion to Dismiss, noncompliance with a regulation is not sufficient to satisfy the very high burden for hauling a doctor into federal court as a criminal drug trafficker. Moreover, no regulatory violations occurred, either with respect to the administering of ketamine or esketamine or with respect to Medicare billing. The Indictment simply has the law wrong.

This Motion adopts the Statement of the Facts and Procedural History sections of the other Motion to Dismiss. We add only that the Counts addressing the "Annual Wellness Visits" (Counts 2 and 15–21), in which the Indictment alleges that Dr. Malik "unjustly enriched" himself involved less than $900.00. The business during this same time period received more than $9.8 million. So the supposed "fraud" listed in the substantive counts 15–21 associated with the Annual Wellness Visits was not even 1/100th of one percent of their receipts. In any event, Dr. Malik reviewed each and every wellness check form with his patients upon seeing them.

LEGAL MEMORANDUM AND ARGUMENT IN SUPPORT OF DISMISSAL

1. Counts 1 and 22 Fail to Properly Charge that Dr. Malik Violated or Conspired to Violate the Crack House Statute.

At all times relevant to the Indictment, Dr. Malik was a psychiatrist licensed to practice medicine in the state of Missouri. Indictment ¶ 1. As a licensed practitioner, Dr. Malik was able to dispense Schedule III controlled substances, including ketamine and esketamine, directly to patients without a written or oral prescription, 21 U.S.C. § 829(b), so long as he obtained annually a registration to do so. 21 U.S.C. § 822(a)(2); Indictment ¶ 2. DEA regulations provide that "[a] separate registration is required for each principal place of business or professional practice at one general physical location where controlled substances are … dispensed by a person." 21 C.F.R. § 1301.12(a); Indictment ¶ 7.[1]

Dr. Malik, through Cedar Plaza LLC, owned the Cedar Plaza Building in South St. Louis County and operates his medical practice there at three different suites: Cedar Plaza Suite 350, which was the "main office" for Psych Care Consultant, L.C.C. ("PCC"), one of Dr. Malik's health care related businesses; Cedar Plaza Suite 220, which was the location of COPE Ketamine Clinic ("COPE"), another of Dr. Malik's health care related businesses; and Cedar Plaza Suite 120, which was the location of Reimbursement Solutions LLC ("RSL"), a medical billing company that conducted billing for PCC and other medical entities associated with Dr. Malik. Indictment ¶¶ 1, 37–39. In other words, PCC, COPE, and RSL were all located on successive

[1] Missouri's counterpart regulation uses substantially the same language as the DEA regulation. *See* Mo. Code Regs. Ann. tit. 19, §30-1.026(3).

floors in the same building and were all part of the same family of businesses operated by Dr. Malik for his medical practice. Indictment ¶¶ 36–39.

Although it is undisputed that Dr. Malik was registered to, and therefore lawfully could, dispense controlled substances directly to patients from Cedar Plaza Suite 350, *see* Indictment ¶¶ 8–10, the Indictment alleges that he was not expressly registered to dispense controlled substances from the COPE office in *Suite 220*, despite it being just one floor beneath another Dr. Malik business, PCC, in Cedar Plaza Suite 350 and just one floor above another Dr. Malik business, RSL, in Cedar Plaza Suite 120. Indictment ¶ 11. According to Counts 1 and 22, this made Suite 220 an illegally maintained drug-involved premises that Dr. Malik made available for the purpose of unlawfully storing and distributing ketamine and esketamine. In other words, the Government's position is that had Dr. Malik brought his patients one floor up for their treatments, he would have been a law-abiding citizen, but because he had them receive their treatments one floor down, he was a drug trafficker. Not only is this theory factually absurd, but it is also legally unsound, as it ignores the fact that Cedar Plaza Suites 350 and 220 were, together, Dr. Malik's "principal place of professional practice at one ***general physical location***" for purposes of the DEA registration requirement, 21 C.F.R. § 1301.12(a) (emphasis added), meaning that Dr. Malik was able to dispense ketamine and esketamine in either suite.

The Indictment suggests that Dr. Malik's DEA registration belongs to the "specific" suite number listed in the DEA registration. But this position would read

the word "general" out of the DEA regulation. According to the Merriam-Webster Dictionary, the word "general" means "involving, applicable to, or affecting the whole," as opposed to "confined by specialization or careful limitation." Available at https://www.merriam-webster.com/dictionary/general. Similarly, at the time the DEA regulation was issued in 1997, Black's Law Dictionary (6th ed. 1990) defined "general" to include "universal, not particularized, as opposed to special." Available at http://tinyurl.com/mtnk2ek8 at 682. Thus, the phrase "general physical location" as used in the DEA regulation must be read to encompass situations in which a space other than the specific area listed in the DEA registration is functionally part of the registrant's professional practice, even if perhaps not technically the same space according to the Post Office. Indeed, if the regulation meant simply "the exact physical location" listed in the DEA registration, there would be no need for the adjective "general" to proceed the term "physical location."

DEA has recognized the flexibility built into its regulation. During the COVID-era, for example, DEA acknowledged that an adjacent parking lot could be considered to fall within the general physical location of a DEA-registered location. *See* COVID-19 FAQ (recognizing that "Neither the CSA nor DEA regulations specifically address whether healthcare providers may dispense controlled substances to patients in the parking lots of their DEA-registered locations" and expressly permitting such practices for the avoidance of doubt during COVID). Available at https://www.deadiversion.usdoj.gov/faq/coronavirus-faq.html

The cases in which offices have been found not to be within "one general physical location" of each other for purposes of the registration requirement typically involve the dispensing of controlled substances miles away from the place of registration, often in an entirely different city or state. *See, e.g.*, *United States v. Clinical Leasing Serv., Inc.*, 759 F. Supp. 310, 314 (E.D. La. 1990), *aff'd*, 925 F.2d 120 (5th Cir. 1991) (dispensing at 1406 St. Charles Avenue in New Orleans, at least three miles away from place of registration at 3480 St. Claude Avenue); *Jeffery J. Becker, D.D.S., and Jeffery J. Becker, D.D.S., Affordable Care Decision and Order*, 77 FR 72387, 72387-88 (Dec. 5, 2012) (dispensing in Avon, Ohio, approximately 40 miles from place of registration in Norwalk, Ohio); *United States v. Shinderman*, No. CRIM. 05-67-P-H, 2006 WL 522105, at *28 (D. Me. Mar. 2, 2006), *adopted as modified*, 432 F. Supp. 2d 149 (D. Me. 2006), *aff'd*, 515 F.3d 5 (1st Cir. 2008) (dispensing in Maine by doctor registered in Illinois); *Joe W. Morgan, D.O.; Decision and Order*, 78 FR 61961-01, 61963-65 (Oct. 8, 2013) (dispensing in Florida by doctor registered in Tennessee). We are aware of no cases in which DEA has found that an office suite located in a building that is owned by a doctor and occupied by two other businesses owned by the same doctor were found not to be "one general physical location."

Given the DEA regulation and the facts alleged in the Indictment, Count 22 and the "drug-involved premises" object of Count 1 fail as a matter of law and should be dismissed. Simply stated, under the facts alleged in the Indictment, there is no conceivable way that two offices, located one floor apart in a building owned by the doctor that houses the doctor's related business on another floor, are not properly

considered part of the same "general physical location" for purposes of the DEA regulation.

Alternatively, the term "general physical location" as used in the DEA regulation is unconstitutionally vague when applied in the criminal context. Even the DEA recognized the regulation was not clear on its own terms in its COVID-19 FAQ quoted above. Count 22 and the "drug-involved premises" object of Count 1 should therefore be dismissed as void for vagueness. *See City of Chicago v. Morales*, 527 U.S. 41, 62 (1999) (finding an "inherently subjective" criminal standard void for vagueness); *Kolender v. Lawson*, 461 U.S. 352, 357 (1983) (criminal laws must have "sufficient definiteness that ordinary people can understand what conduct is prohibited").

2. The Drug Trafficking Counts (Counts 1, 5, and 6) Cannot Be Premised on an Alleged REMS Violation.

According to the Indictment, Dr. Malik was enrolled in the Spravato Risk Evaluation and Mitigation Strategy Program (the "REMS Program") beginning in approximately December 2020. Indictment ¶ 45. The active ingredient in Spravato, a prescription nasal spray indicated for certain types of depression, is esketamine. The Indictment alleges that the REMS Program requires, among other things, that Spravato be administered under the direct supervision of "a healthcare provider," that "a healthcare provider" be onsite to monitor the patient for at least two hours following the administration of Spravato, and that "a prescriber" be onsite during Spravato administration and monitoring. Indictment ¶ 21. According to Counts 1, 5, and 6, Dr. Malik and Dr. Ali violated 21 U.S.C. §§ 841 and 846 because Dr. Ali

administered Spravato outside of the presence of and without direct supervision of Dr. Malik. Indictment ¶¶ 46, 59. These charges are fatally deficient for at least two reasons.

First, according to the Indictment, the REMS program did not require ***Dr. Malik specifically*** to supervise or be onsite during or immediately after Dr. Ali's administration of Spravato. Rather, the Indictment alleges merely that "***a*** healthcare provider" and "***a*** prescriber" must perform these functions; it does not allege that Dr. Malik had to be "***the*** healthcare provider" or "***the*** proscriber" for the patient or Spravato treatment at issue. Because the REMS program uses the indefinite article "a," the Indictment cannot legally charge Dr. Malik specifically with violating 21 U.S.C. §§ 841 and 846 without also alleging that there was ***no*** healthcare provider at all who supervised or was present for the Spravato treatments alleged in the Indictment. Accordingly, Counts 5 and 6 and the Spravato-related object of Count 1 must be dismissed.

Second, and separately, we are aware of no case in which a REMS program has formed the basis of a 21 U.S.C. §§ 841 or 846 violation. And this is for good reason. Under the U.S. Food Drug and Cosmetic Act ("FD&C Act"), which establishes the U.S. Food and Drug Administration's ("FDA") REMS authority, the FDA may require a drug application holder (*i.e.*, the drug manufacturer) to enter into agreements with healthcare providers. 21 U.S.C. § 355-1(e)(3). The FD&C Act does not authorize the FDA to enter into agreements with healthcare providers directly or to ensure that healthcare providers are complying with their agreements with the drug application

holder. Rather, it is the drug application holders that must oversee healthcare provider compliance with the agreements. It is not at all surprising, then, that the FD&C Act enumerates only consequences *to the drug manufacturer for violating the REMS*. *See* 21 U.S.C. §§ 333(b)(4), 352(y).[2] The FD&C Act does not provide any mechanism for holding healthcare providers liable for violating their agreements with a drug application holder under a REMS agreement, and any attempt to do so under the drug trafficking offenses is without authority.[3] Accordingly, Counts 5 and 6 and the Spravato-related object of Count 1 must be dismissed because they are inconsistent with the statutory framework of the FD&C Act.

3. Counts 2 and 15–21 Are Based on the Faulty Legal Premise that Dr. Ali's Services Were Not Reimbursable by the Medicare Program.

According to Counts 2 and 15–21, Dr. Malik committed health care fraud and made false statements in connection with Medicare claims because Dr. Malik billed Medicare for services performed by Dr. Ali—specifically five Annual Wellness Visits, one office visit, and one prolonged office or other outpatient evaluation, all totaling less than $900. Indictment ¶¶ 53–55, 61, Counts 15–21. But these counts are based on a fundamentally incorrect legal proposition—that Dr. Ali's services were not reimbursable by Medicare under the facts alleged in the Indictment—and therefore must be dismissed.

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[2] The "responsible person" referenced in these provisions is defined as "the person submitting a covered application or the holder of the approved such application." 21 U.S.C. § 355-1(b)(7). Again, this is not the healthcare provider.

[3] With respect to the Spravato REMS specifically, Janssen is the drug application holder responsible for monitoring the compliance of—and deciding the appropriate corrective actions for—the healthcare providers enrolled in the Spravato REMS program. *See* http://tinyurl.com/2xk647xr at 6–7.

a. The Indictment Fails to Allege a Violation Related to the Annual Wellness Visits.

The Indictment alleges that Dr. Ali and Dr. Malik "falsely stated and represented in claims for payment [for Annual Wellness Visits] that services were rendered by Dr. Malik when, in fact, they were rendered by Dr. Ali, whose services were not reimbursable by the Medicare program . . . ." Indictment ¶ 61.

Medicare Part B generally pays for first and subsequent Annual Wellness Visits furnished to eligible beneficiaries if they are furnished by a health professional. *See* 42 C.F.R. § 410.15(b). The regulation defines initial and subsequent Annual Wellness Visits as "visit[s] providing personalized prevention plan services . . . furnished to an eligible beneficiary by a ***health professional***[.]" 42 C.F.R. § 410.15(a) (emphasis added). The definition of a "health professional" expressly includes "[a] ***medical professional*** (***including*** a health educator, a registered dietitian, or nutrition professional, or ***other licensed practitioner***) . . . ***working under the direct supervision . . . of a physician*** . . . ." *Id.* (emphasis added). The regulation does not require that the "other licensed practitioner" independently be enrolled in Medicare.

Thus, to the extent that Counts 2 and 15–19 are based on the theory that there were no circumstances under which Dr. Malik, who was enrolled in Medicare, *see* Indictment ¶ 28, could legally bill for Annual Wellness Visits performed by Dr. Ali, "a medical doctor, licensed to practice medicine in the state of Missouri," *see* Indictment ¶ 2, they must be dismissed as a matter of law.

To the extent that Counts 2 and 15–19 are based on the theory that Dr. Malik could not bill for Annual Wellness Visits performed by Dr. Ali because Dr. Malik was not present in the office when Dr. Ali performed the visits, they also must be dismissed as a matter of law. This is because the in-person requirement for "direct supervision" was suspended beginning in March 31, 2020, well before the events at issue in Counts 2 and 15–19.

As noted above, Dr. Malik could bill for Annual Wellness Visits that Dr. Ali conducted under Dr. Malik's "direct supervision." In April 2020, the Centers for Medicare & Medicaid Services (CMS) determined that, for the duration of the COVID-19 emergency, direct supervision would no longer require the supervising physician's physical presence at the time of service. In particular, CMS amended the definition of "direct supervision" in 42 C.F.R. § 410.32(b)(3)(ii) to include "virtual presence through audio/video real-time communications technology . . . ." 85 Fed. Reg. 19230, 19286 (Apr. 6, 2020); 85 Fed. Reg. 84472, 85026 (Dec. 28, 2020). CMS believed that individual practitioners were "in the best position to make decisions about how to meet the [direct supervision] requirement," and later clarified in response to a commenter question that, pursuant to the amended language, the supervising practitioner "does not need to be virtually present throughout the performance of the procedure," but rather "need[s] to be immediately available to provide the virtual presence whenever necessary." 85 Fed. Reg. 84472, 84538 (Dec. 28, 2020); 88 Fed. Reg. 78818, 78880 (Nov. 16, 2023).

The Annual Wellness Visits charged in the Indictment were performed in December 2020 and January 2021, months after the "virtual presence" policy went into effect. *See* Indictment ¶ 49 ("Beginning in or about December 2020"), Counts 15-19 (listing Annual Wellness Visits performed on five days between December 11, 2020 and January 11, 2021). Thus, to the extent that the Government contends that the Medicare claims were improper because Dr. Malik was not physically present when Dr. Ali rendered the services at issue (and therefore that Dr. Ali was not under Dr. Malik's "direct supervision"), Counts 15–19 and the Annual Wellness Visit object of Count 2 must be dismissed.

In summary, Dr. Ali could properly perform the Annual Wellness Visits as a "medical professional" who was a "licensed practitioner" (i.e., physician licensed to practice medicine) working under the "direct supervision" of Dr. Malik. Dr. Malik was therefore permitted to bill for Annual Wellness Visits performed by Dr. Ali because Dr. Ali was both (1) a "health professional" and (2) working under the direct supervision of Dr. Malik. Counts 2 and 15–19 should be dismissed.

b. The Indictment Fails to Allege a Violation Related to the Services Provided to T.A.

Counts 20 and 21 of the Indictment are based on the theory that Dr. Malik "falsely stated and represented in claims for payment that services [provided to a patient with the initials T.A.] were rendered by Dr. Malik when, in fact, they were rendered by Dr. Ali, whose services were not reimbursable by the Medicare program . . . ." Indictment ¶ 61. Thus, these Counts are also based on the faulty premise that Dr. Ali's services were not reimbursable.

Medicare Part B generally pays for services and supplies furnished "incident to" the service of a physician. 42 C.F.R. § 410.26. Medicare regulations set forth several requirements for "incident to" billing, including that "only the supervising physician … may bill Medicare for incident to services." *Id.* at (b)(5). The Indictment is therefore incorrect that there were no circumstances under which Dr. Malik could bill for services performed by Dr. Ali, because the regulation permits him to bill for services furnished by auxiliary personnel working under his direct supervision.

Dr. Ali meets the definition of auxiliary personnel:

> Auxiliary personnel means ***any individual*** who is ***acting under the supervision of a physician*** (or other practitioner), regardless of whether the individual is an employee, leased employee, or independent contractor of the physician (or other practitioner) or of the same entity that employs or contracts with the physician (or other practitioner), ***has not been excluded from the Medicare, Medicaid and all other federally funded health care programs by the Office of Inspector General or had his or her Medicare enrollment revoked***, *and* ***meets any applicable requirements to provide incident to services, including licensure, imposed by the State in which the services are being furnished***.

42 C.F.R. § 410.26(a)(1).

First, Dr. Ali constitutes an "individual." Physicians are not carved out of this definition. In fact, in discussing "incident to" regulations, CMS explicitly endorsed a physician billing for services performed by another physician. 66 Fed. Reg. 55246, 55268 (Nov. 1, 2001) ("We deliberately used the term any individual so that the physician (or other practitioner), under his or her discretion and license, may use the service of anyone ranging from another physician to a medical assistant.").

Second, Dr. Ali was acting under the supervision of a physician, namely Dr. Malik. Most services must be furnished under the direct supervision of a physician

to be reimbursable. *See* 42 C.F.R. § 410.26(b)(5). "Direct supervision" is defined by 42 C.F.R. § 410.26(a)(2), which, for the reasons discussed above, did not require that Dr. Malik be physically present at the time that the services were rendered to T.A.

Third, Dr. Ali met the requirement that "auxiliary personnel" must not be "excluded from the Medicare, Medicaid and all other federally funded health care programs by the Office of Inspector General or had his or her Medicare enrollment revoked . . . ." 42 C.F.R. § 410.26(a)(1). The Indictment does not allege that Dr. Ali has been excluded by the Office of Inspector General—because he has not been.[4] The Indictment alleges that had Dr. Ali reported to Medicare that he had been "suspended" from the Missouri Medicaid program, he "would have been revoked" from Medicare, *see* Indictment ¶ 32, but that does not change the fact that Dr. Ali had ***not*** had his Medicare enrollment revoked at the times alleged in the Indictment. It also reflects a misunderstanding of Medicare regulations.

CMS has discretion on whether to revoke a Medicare enrollment based on sanctions imposed by state Medicaid programs and can only revoke if the provider is "terminated, revoked or otherwise barred from participation and has exhausted all appeal rights. *See* 42 C.F.R. § 424.535(a)(12). Dr. Ali has not been "terminated, revoked, or otherwise barred from participation" in the Missouri Medicaid program.[5] This is consistent with the scope of CMS reporting requirements during Medicare

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[4] *See* U.S. Dep't of Health & Hum. Servs., Office of Inspector General, *Search the Exclusions Database*, *available at* https://exclusions.oig.hhs.gov/.

[5] *See* Missouri Dep't of Social Servs., *Provider Sanctions List*, available at https://mmac.mo.gov/providers/provider-sanctions/.

enrollment, which does not consider temporary state program suspensions to be reportable final adverse actions, but rather only requires the reporting of a "Medicaid exclusion, revocation, or termination of any billing number."[6]

Fourth, Dr. Ali was licensed to perform the billed services as "a medical doctor, licensed to practice medicine in the state of Missouri." Indictment ¶ 2.

In summary, because Dr. Ali was acting as "auxiliary personnel" and the remaining requirements of 42 C.F.R. § 410.26(b) were also satisfied, the services described in Counts 20–21 were properly billed to the Medicare program as services incident to Dr. Malik's services under the facts alleged in the Indictment, and Counts 20–21, as well as Count 2 to the extent it relies on a similar theory, must be dismissed.

Conclusion

Dr. Malik is a good and honest doctor, who enjoys an impeccable reputation in this community. This Indictment has unfairly tarnished that well-deserved and hard-earned reputation. And why? Because, according to the Indictment, he violated a number of regulations, like listing the wrong suite number. But the Government misinterpreted those regulations. Dr. Malik did not violate them and this Indictment should be dismissed, allowing Dr. Malik the chance to earn back his reputation.

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6 *See* U.S. Dep't of Health & Hum. Servs., Ctrs. for Medicare & Medicaid Servs., *Medicare Program Integrity Manual*, Chapter 10 – Medicare Enrollment § 10.1.1 "final adverse action," available at http://tinyurl.com/5n6kfd4v. CMS similarly has discretion whether to revoke a provider's enrollment in Medicare for failure to comply with reporting requirements. *See* 42 C.F.R. § 424.535(a)(9).

Respectfully submitted,

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